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I, JONNE YABSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002953469 for a patent by COCHLEAR LIMITED as filed on 19 December 2002.

WITNESS my hand this
Ninth day of January 2004

J R Yabsley

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AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Stylet with plug for sealing a lumen in an electrode array

The invention is described in the following statement:

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable cochlear electrode assembly.

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a processor unit, and an implanted internal component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that

converts the detected sounds and particularly speech into a coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the receiver/stimulator unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit typically includes the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The external componentry of the cochlear implant has been traditionally carried on the body of the implantee, such as in a pocket of the implantee's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip mounted behind the ear or on a clothing lapel of the implantee.

More recently, due in the main to improvements in technology, the physical dimensions of the speech processor have been able to be reduced allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the implantee. This unit has allowed the microphone, power unit and the speech processor to be housed in a single unit capable of being discretely worn behind the ear, with the external transmitter coil still positioned on the side of the user's head to allow for the transmission of the coded sound signal from the speech processor and power to the implanted stimulator unit.

Together with improvements in available technology, much research has been undertaken in the area of understanding the way sound is naturally processed by the human auditory system. With such an increased understanding of how the cochlea naturally processes sounds of varying frequency and magnitude, there is a need to provide an improved cochlear implant system that delivers electrical stimulation to the auditory nerve in a way that takes into account the natural characteristics of the cochlea.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region being responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing the electrode assembly with an array of electrodes, each electrode being arranged and constructed to deliver a cochlea stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode stimulate the cilia disposed on the modiolus of the cochlea. Several electrodes may be active simultaneously.

It has been found that in order for these electrodes to be effective, the magnitude of the currents flowing from these electrodes and the intensity of the corresponding electric fields, are a function of the distance between the electrodes and the modiolus. If this distance is relatively great, the threshold current magnitude must be larger than if the distance is relatively small. Moreover, the current from each electrode may flow in all directions, and the electrical fields corresponding to adjacent electrodes may overlap, thereby causing cross-electrode interference. In order to reduce the threshold stimulation amplitude and to eliminate cross-electrode interference, it is advisable to keep the distance between the electrode array and the modiolus as small as possible. This is best accomplished by providing the electrode array in the shape which generally follows the shape of the modiolus. Also, this way of delivering the electrical stimulation to the auditory nerve is most effective as the electrode contacts are as close as possible to the auditory nerves that are particularly responsive to selected pitches of the sound waves.

In order to achieve this electrode array position close to the inside wall of the cochlea, the electrode needs to be designed in such a way that it assumes this position upon or immediately following insertion into the cochlea. This is a challenge as the array needs to be shaped such that it assumes a curved shape to conform with the shape

of the modiolus and must also be shaped such that the insertion process causes minimal trauma to the sensitive structures of the cochlea. In this sense, it has been found to be desirable for the electrode array to be generally straight during the insertion procedure.

Several procedures have been adopted to provide an electrode assembly that is relatively straightforward to insert while adopting a curved configuration following insertion in the cochlea. In one case, a straight platinum wire stylet is positioned within a lumen extending along at least a portion of the length of the assembly. The stylet is relatively stiffer than the body of the assembly and serves to hold a pre-curved electrode array in a generally straight configuration up until insertion. Following insertion, the platinum stylet is withdrawn from the lumen allowing the array to return to its pre-curved configuration.

The presence of any lumen within the electrode assembly for the stylet may pose a potential pathway for pathogens including harmful bacteria, to migrate from a location external the cochlea into the cochlea if there is an opening from the lumen into the cochlea.. While most implants are typically designed and constructed to ensure there is no potential pathway, other circumstances may dictate that such a lumen or an opening from such a lumen is desirable. In this case, the present invention provides a mechanism for preventing any potential migration of pathogens through the assembly.

While the above description of the prior art is directed to cochlear implant electrode assemblies, similar issues of potential pathogen migration arise in other implantable devices using electrode assemblies, such as midbrain implants and muscle stimulation systems used in function electronic stimulation (FES) systems.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and having at least one electrode mounted thereon;

a lumen extending into and along at least a portion of the elongate member from an orifice positioned at or relatively closer to the proximal end than the distal end;

a stiffening element positioned at least partially within the lumen and extending out of the lumen through said orifice; and

a sealing member mountable to the stiffening element;

wherein the stiffening element is movable relative to the orifice of the lumen between a first position in which the sealing member mountable thereon does not seal the lumen and a second position in which the sealing member at least substantially seals the lumen.

According to a second aspect, the present invention is a stiffening element of an elongate member of a tissue-stimulating device, the stiffening element being positionable within the lumen of the elongate member and adapted to extend from the lumen through an orifice to a location external the lumen, the stiffening element comprising:

a stiffening member; and

a sealing member mountable to the stiffening member;

wherein the stiffening element is movable relative to the orifice of the lumen between a first position in which the sealing member mountable thereon does not seal the lumen and a second position in which the sealing member at least substantially seals the lumen.

In a preferred embodiment, the stiffening element can be formed from a non-bioresorbable material. In this embodiment, the stiffening element can comprise a metallic stylet, or a stylet-like element formed from any other suitable stiffening material, extending through the lumen in the elongate member. In one embodiment, the stylet can be formed from a biocompatible metal, a biocompatible metallic alloy or

a biocompatible relatively stiff plastic. In a preferred embodiment, a metal stylet can be formed from platinum.

In the case of a metal stylet, the stylet can extend out of the orifice through a seal formed in the orifice allowing the stylet to be manipulated and removed from the lumen during or following insertion of the device.

In a further embodiment, the sealing member can comprise a sealing portion of a resiliently flexible material mounted to the stiffening member of the stiffening element. The material can be movable relative to the stiffening member. In one embodiment, the material can comprise a biocompatible silicone. In this and other embodiments, the sealing portion can be cylindrical in form.

During manufacture and/or placement of the stiffening member in the lumen of the elongate member, the portion of resiliently flexible material is preferably initially mounted adjacent a distal end of the stiffening member and within the lumen of the elongate member, ie a first position. On relative removal of the stiffening member from the lumen, the sealing portion preferably remains mounted to the stiffening member and is drawn through the lumen towards the orifice of the lumen. In a preferred embodiment, the orifice of the lumen is preferably smaller in diameter than at least the majority of the lumen. As the stiffening member relatively withdraws, the sealing portion eventually abuts the inner wall of the lumen where it narrows to form the orifice. In one embodiment, this abutment of the sealing portion can act to at least substantially seal the orifice. In another embodiment, the sealing portion can be at least partially drawn into the narrowing of the lumen and so form a seal therewith. In these embodiments, with the sealing member now in the second position, further withdrawing force on the stiffening member can serve to disengage the stiffening member from the sealing portion so allowing the stiffening member to be fully withdrawn through the orifice.

In another embodiment, the sealing portion can be non-removably mounted at or relatively near the distal end of the stiffening member. In this case, on relative withdrawal of the stiffening member from the lumen, the sealing portion is again carried into sealing abutment or engagement with the narrowing of the lumen. Once in this position, the stiffening member can be severed at or adjacent the orifice so leaving

the sealing portion with a relatively short portion of the stiffening member embedded therein in the orifice of the lumen.

In a still further embodiment, the sealing member can be an integral part of the stiffening member.

In yet another embodiment, the sealing member can have a shape that matches the shape of the narrowing of the lumen at or adjacent the orifice thereof. For example, the narrowing of the lumen can comprise a frusto-conical region with the lumen narrowing towards the orifice. In this embodiment, the sealing member can also be at least partially frusto-conical in form and shaped to match the taper of the narrowing portion of the lumen.

In the above embodiments, the sealing member can be formed of a material different to that making up the elongate member. Where the elongate member is made of a silicone, the sealing member is preferably formed of a material having a relatively lower coefficient of friction. For example, the material can be formed of an epoxy material, platinum, iridium and/or can have a parylene coating. The sealing member can also have a lubricious coating.

In a still further embodiment, the sealing member can comprise a substantially spherical or spherical member mounted at or relatively near the distal end of the stiffening member. In another embodiment, the member can have another shape. Where the stiffening member is a metal stylet, the sealing member can be a platinum sphere (or a plastic sphere) mounted to the distal end of the stylet. The sphere can be integrally or non-integrally mounted to the distal end. In this embodiment, the diameter of the stylet can be about 0.125mm, while the sphere can have a diameter larger than the stylet, for example about 0.15mm.

In this embodiment, the narrowing of the lumen adjacent the orifice is preferably shaped to receive the sphere at the end of the stylet. In this regard, the region can comprise a spherical region shaped to receive the sphere. In one embodiment, the spherical region can have a diameter less than that of the sphere of the stylet. For example, where the sphere has a diameter of about 0.15mm or more, the spherical region can have a diameter of about 0.12mm or less. The spherical region can be located a relatively short distance from the orifice of the lumen. In one embodiment,

the spherical region can be spaced a distance of about 0.3mm from the orifice. In this region, the lumen can comprise a cylindrical region having a diameter less than that of the spherical region, for example, 0.1mm or less. A further cylindrical region of the lumen can also extend from the spherical region into the elongate member before the lumen expands to a larger diameter. The further cylindrical region can have a diameter of about 0.1mm and a length of about 0.2mm or more. The remainder of the lumen preferably has a diameter of about 0.18mm for at least a majority of its length.

In this embodiment, it will be appreciated that as the surgeon relatively withdraws the stylet from the lumen, the surgeon will note the increase in friction as the sphere enters the smaller diameter cylindrical region on the distal side of the spherical region. On noticing this increase, the surgeon would be aware to slow the rate of relative withdrawal until the surgeon notes that the sphere has entered the spherical region. At this time, the surgeon would stop withdrawal and trim the stylet at or adjacent the orifice. The presence of the sphere positioned in the spherical region serves to at least substantially seal the orifice of the lumen.

In a preferred embodiment of this invention, the device is a cochlear implant electrode assembly. In another embodiment, the device is adapted to deliver stimulation to the brain, such as the midbrain. Still further, the device can be adapted to deliver functional electrical stimulation to one or more muscle groups in the body of an implantee.

In a further embodiment, the distal end of the elongate member is adapted to be inserted firstly into the implantee.

The lumen can be cylindrical or have any other suitable cross-sectional shape. In one embodiment, the lumen extends through the elongate member for a substantial portion of its length. In a further embodiment, the lumen extends from an opening at the proximal end of the elongate member to a position that is adjacent the distal end thereof.

In a further embodiment, the elongate member can have a plurality of electrodes mounted thereon. In one embodiment, the electrodes can be formed of a biocompatible metallic material, such as platinum.

In a further embodiment, the elongate member can have a first configuration selected to allow said member to be more readily inserted into an implantee's body, such as the cochlea, and a second configuration wherein said elongate member is more readily adapted to apply a preselected tissue stimulation with the electrodes. In a further embodiment, the elongate member can have at least one intermediate configuration between said first and second configurations.

In a still further embodiment, at least a portion of the outer surface of the elongate member can have a coating of lubricious material. In a further embodiment, a substantial portion of the outer surface can have a coating of the lubricious material. In a still further embodiment, the entire outer surface of the elongate member can have a coating of the lubricious material.

The lubricious material preferably becomes lubricious on being brought into contact with a fluid, such as a saline solution. Still further, the coating preferably becomes lubricious on being brought into contact with a body fluid, such as cochlear fluid.

In one embodiment, the lubricious material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used.

In yet another embodiment, the stiffening element can be made of a second material relatively stiffer than the resiliently flexible material of the elongate member. The stiffening element can be adapted to bias the elongate member into the first configuration.

In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

The elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration.

In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment, the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as Silastic MDX 4-4210. In another embodiment, the elongate member can be formed from a polyurethane or similar material.

Once implanted, the electrodes can receive stimulation signals from a stimulator device. The stimulator device is preferably electrically connected to the elongate member by way of an electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to a stimulator device or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator device, required to connect the wires extending from the electrodes to the stimulator device. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator device.

The stimulator device is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator device is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator device, a receiver device. The receiver device is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver device and vice versa. The receiver device can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals.

While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator device using the transmitter and receiver coils. The implanted receiver/stimulator device demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted receiver/stimulator device and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator device.

According to yet a further aspect, the present invention is a method of placing an implantable tissue-stimulating device as defined herein in the body of an implantee, the method comprising the steps of:

(i) inserting the elongate member into a desired location in the body of the implantee;

(ii) during and/or after insertion, relatively withdrawing the stiffening element from the lumen through the orifice; and

(iii) bringing the sealing member that is mountable to the stiffening element into a position in which the sealing member at least substantially seals the lumen.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial representation of a prior art cochlear implant system;

Fig. 2 is a fragmentary view of a portion of a stylet having a sealing member movably mounted thereto;

Fig. 3 is a fragmentary view of an elongate member having a sealing member positioned within the lumen following withdrawal of the stylet;

Fig. 4 is a fragmentary view of an elongate member having a sealing member mounted to a severed stylet and positioned at least adjacent the orifice of the lumen;

Fig. 5 is a fragmentary view of a further embodiment of the present invention;

Fig. 6a is a view of a stylet having a sphere at a distal end thereof;

Fig. 6b is a fragmentary view of an elongate member adapted for use with the stylet of Fig. 6a; and

Fig. 6c depicts the stylet of Fig. 6a sealably positioned within the elongate member of Fig. 6b.

Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of a typical cochlear implant system with reference to Fig. 1.

Cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 which transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

The internal component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4532930.

While directed to cochlear implants, it will be appreciated that the present invention can apply equally to other tissue-stimulating devices, such as devices adapted to deliver electrical stimulation to the brain or muscles of an implantee.

One embodiment of a stiffening element according to the present invention is depicted generally as 30 in Fig. 2. The depicted stiffening element is formed of platinum but it will be appreciated that other biocompatible metals and plastics materials or combinations thereof could be employed as a stylet in the present invention. The stylet 30 is relatively stiffer than the silicone elongate member depicted as 40 in Fig. 3 and is adapted to be positioned within a lumen 41 thereof and so straighten the elongate member 40 from its preferentially curved configuration to one that is more readily implantable in the cochlea of an implantee.

The stylet 30 has a distal end 31 and has prior to its relative withdrawal from the lumen 41 a cylindrical resiliently flexible sealing portion 32 that is tethered thereto through tether 33. During manufacture and/or placement of the stylet 30 in the lumen 41 of the elongate member 40, the sealing portion 32 is preferably initially mounted adjacent the distal end 31 and within the lumen 41 of the elongate member, ie a first position. On relative removal of the stylet 30 from the lumen 41, the sealing portion 32 remains tethered to the stylet and is drawn through the lumen 41 towards the orifice 42 thereof. As depicted, the orifice 42 of the lumen 41 is typically smaller in diameter

than at least the majority of the lumen 41. As the stylet 30 relatively withdraws, the sealing portion 32 eventually abuts the inner wall of the lumen where it narrows adjacent the orifice, ie narrow region 43. This abutment of the sealing portion 32 acts to at least substantially seal the lumen 41.

In another embodiment, the sealing portion 32 can be at least partially drawn into the narrow region 43 of the lumen 41 and so form a seal therewith. In these embodiments, with the sealing portion 32 now in the second position, further withdrawing force on the stylet 30 serves to disengage the stylet 30 from the sealing portion 32 so allowing the stylet 30 to be fully withdrawn through the orifice 42.

In another embodiment depicted in Fig. 4, the sealing portion 32a can be non-removably mounted at or relatively near the distal end 31a of the stylet 30a. In this case, on relative withdrawal of the stylet 30a from the lumen 41, the sealing portion 32a is again carried into sealing abutment or engagement with the narrow region 43 of the lumen. Once in this position, the stylet 30a can be severed at or adjacent the orifice 42 so leaving the sealing portion 32a with a relatively short portion of the stylet 30a embedded therein in the narrow region 43 of the lumen.

In a still further embodiment depicted in Figs. 5 to 6c, the sealing member can be an integral part of the stylet.

In Fig. 5, the sealing member 32c has a shape that matches the shape of the narrow region 43c of the lumen at or adjacent the orifice 42 thereof. As depicted, the narrow region 43c can comprise a frusto-conical region with the lumen narrowing towards the orifice 42. In this embodiment, the sealing member 32c is also at least partially frusto-conical in form and shaped to match the taper of the narrow region 43c.

In these embodiments, the sealing members can be formed of a material different to that making up the elongate member. Where the elongate member is made of a silicone, the sealing member is preferably formed of a material having a relatively lower coefficient of friction. For example, the material can be formed of an epoxy material, platinum, iridium and/or can have a parylene or lubricious coating.

As depicted in Figs. 6a to 6c, the sealing member can comprise a spherical member 32d mounted at the distal end of a stylet 30d. Where the stylet 30d is a metal

stylet, the sealing member can be a platinum sphere mounted to and/or integral with the distal end of the stylet. The depicted sphere 32d is integrally mounted to the distal end of the stylet 30d. In this embodiment, the diameter of the stylet can be about 0.125mm, while the sphere can have a diameter of about 0.15mm.

In this embodiment, the narrowing of the lumen 41 adjacent the orifice is shaped to receive the sphere 32d at the end of the stylet 30d. In this regard, the region comprises a spherical region 50 shaped to receive the sphere 32d. In this embodiment, the spherical region 50 has a diameter less than that of the sphere 32d. For example, where the sphere 32d has a diameter of about 0.15mm, the spherical region 50 can have a diameter of about 0.12mm. The spherical region 50 is located a relatively short distance from the orifice 42. In the depicted embodiment, the spherical region 50 is spaced a distance of about 0.3mm from the orifice 42. In this region, the lumen can comprise a cylindrical region 51 having a diameter less than that of the spherical region 50, for example, 0.1mm. A further cylindrical region 52 of the lumen also extends from the spherical region 50 into the elongate member before the lumen expands to a larger diameter. The further cylindrical region 52 can have a diameter of about 0.1mm and a length of about 0.2mm. The remainder of the lumen preferably has a diameter of about 0.18mm for at least a majority of its length.

In this embodiment, it will be appreciated that as the surgeon relatively withdraws the stylet 30d from the lumen, the surgeon will note the increase in friction as the sphere enters the smaller diameter cylindrical region 52 on the distal side of the spherical region 50. On noticing this increase, the surgeon would be aware to slow the rate of relative withdrawal until the surgeon feels that the sphere 32d has entered the spherical region 50. One or more indicators could also be provided on the stylet to indicate to the surgeon to slow the withdrawal when the indicators come out of the proximal end of the lumen. At this time, the surgeon would stop withdrawal and trim the stylet 30d at or adjacent the orifice. The presence of the sphere 32d positioned in the spherical region 50, as depicted in Fig. 6c, serves to at least substantially seal the lumen.

The depicted elongate members are preferably preformed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as Silastic MDX 4-4210. In another embodiment, the elongate member can be formed from a polyurethane or similar material.

Once implanted, the electrodes of the elongate member can receive stimulation signals from a stimulator device. The stimulator device is preferably electrically connected to the elongate member by way of the electrical lead 21.

In one embodiment, the lead can extend from the elongate member to a stimulator device or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator device, required to connect the wires extending from the electrodes to the stimulator device. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator device.

The stimulator device is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator device is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator device, a receiver device. The receiver device is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver device and vice versa. The receiver device can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the

pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator device using the transmitter and receiver coils. The implanted receiver/stimulator device demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted receiver/stimulator device and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator device.

The effective delivery of electrode arrays can often be dependent on the use of stylets that are positioned within a lumen of the array. The present invention provides a means of still allowing use of such arrangements while ensuring that the lumen does not subsequently become a pathway for transfer of pathogens through the array and into the implantee.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this nineteenth day of December 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

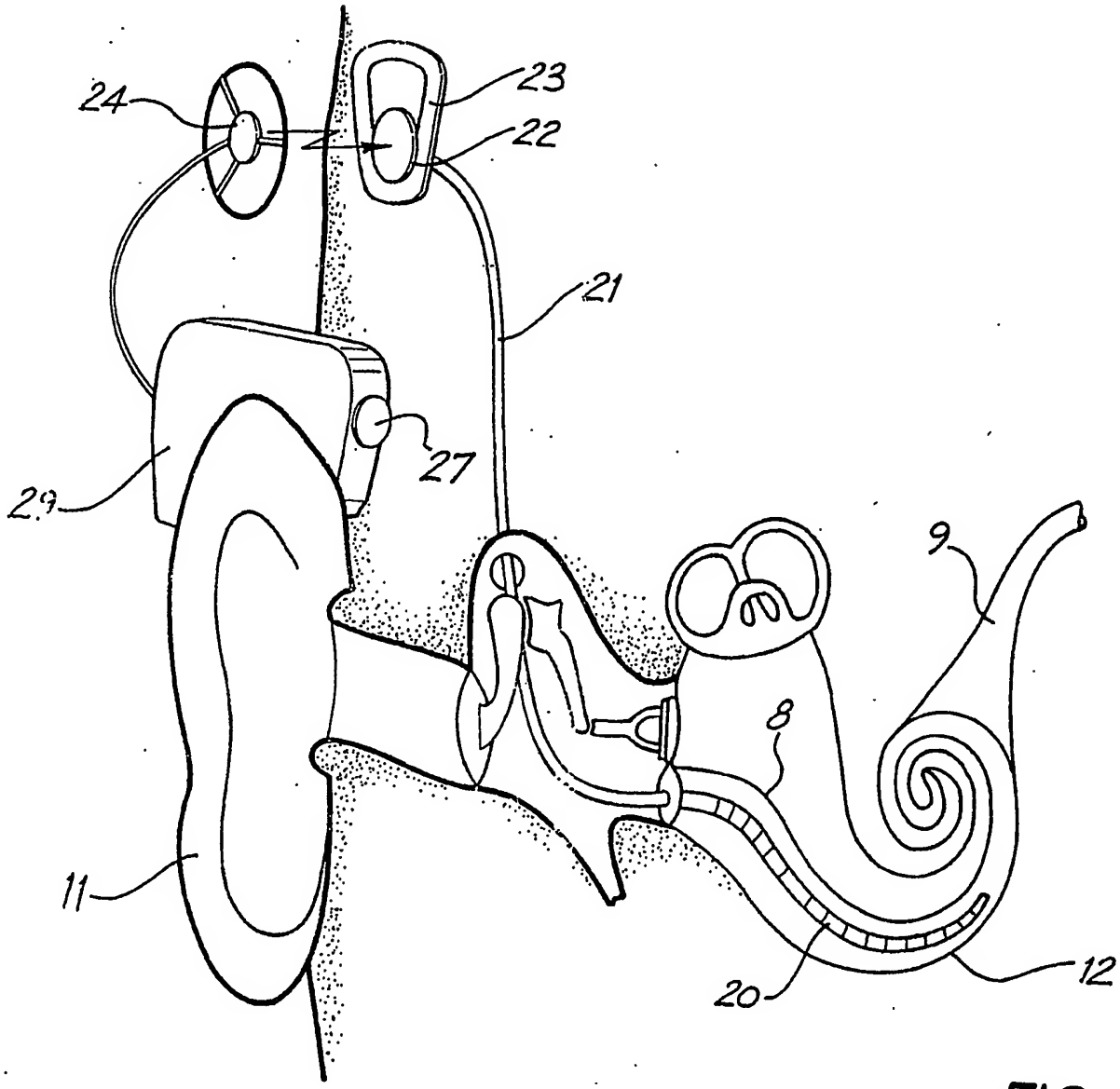

FIG. 1

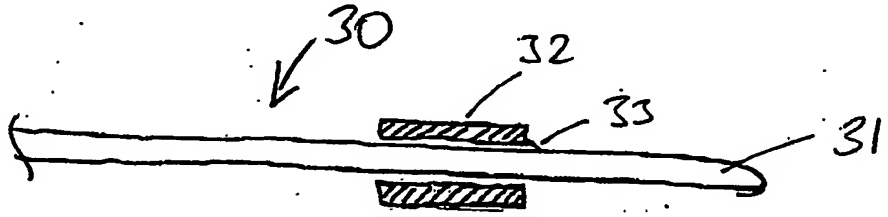

Figure 2

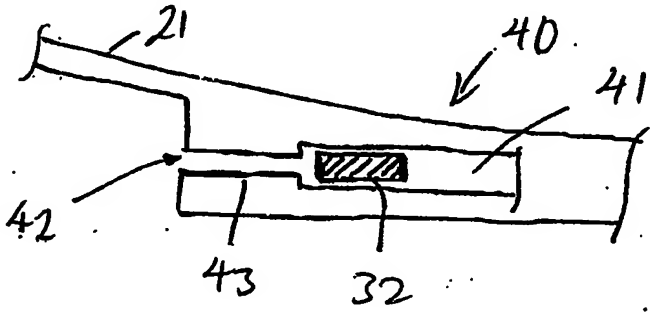

Figure 3

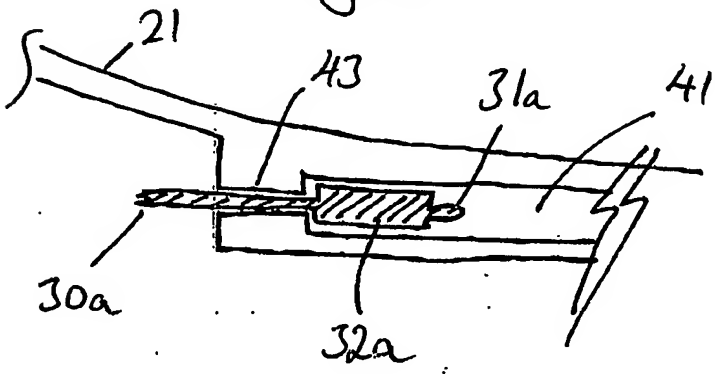

Figure 4

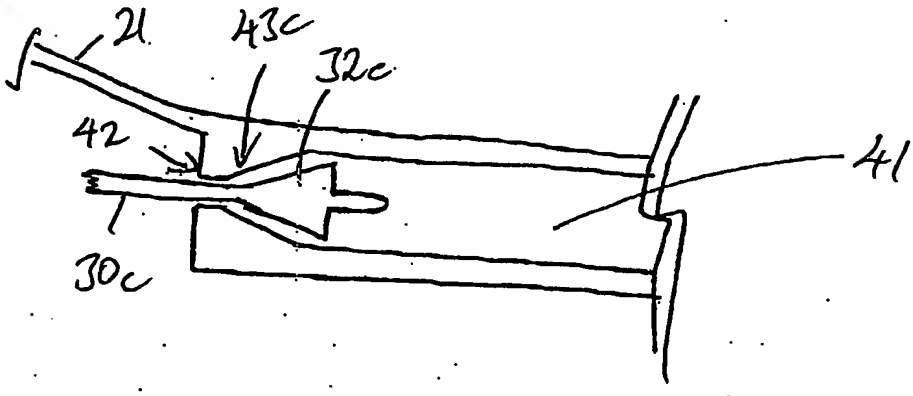

Figure 5

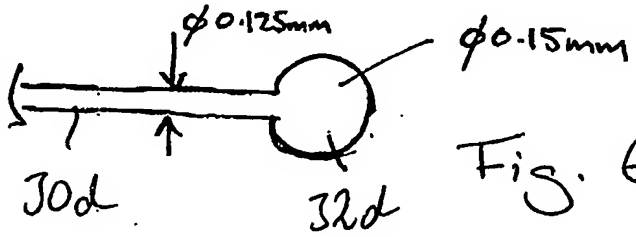

Fig. 6a

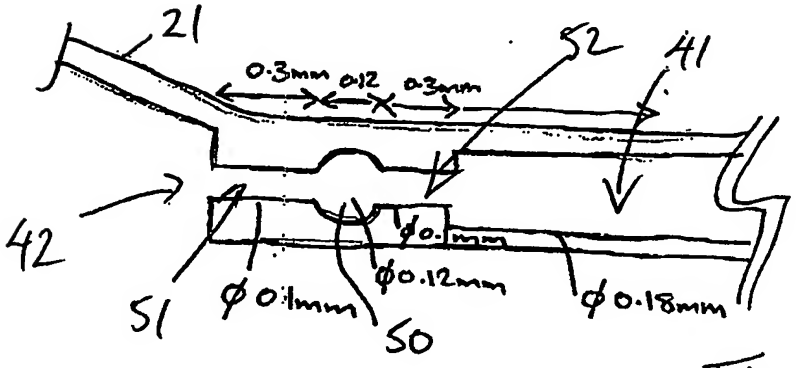

Fig. 6b

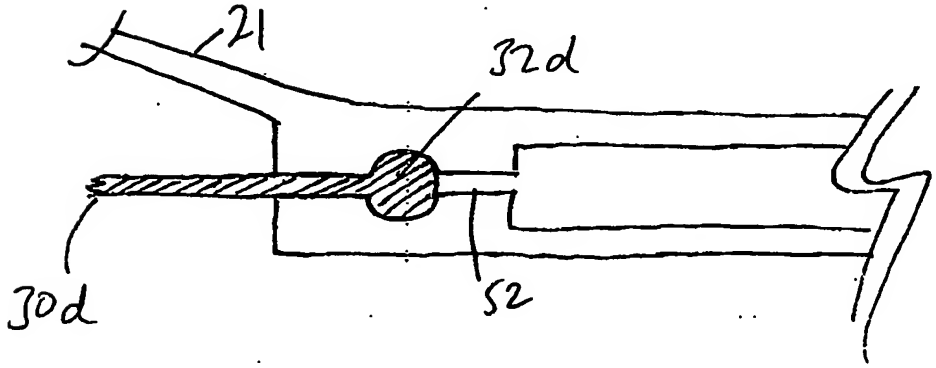

Figure 6c

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